

Remarks

Applicants' representative, the undersigned, thanks the Examiner for the courteous interview which was held on August 16, 2004. During the interview, the rejections of record, proposed amended claims and proposed new claims were discussed. Substantive items discussed during the interview are provided along with the remarks herein addressing each issue.

The amendments made in the present submission are summarized as follows.

Applicants have amended the Abstract to note use of the compounds of the invention in the treatment of obesity, as required by the Examiner.

Claim 1 has been deleted.

Claim 2 has been amended to render it in independent format, and to delete the option for R1, R2, R3 and R4 of "heterocyclyl". Amended claim 2 is an independent claim directed to a compound of formula (I). The subject matter of amended claim 2 obtains support from the priority application, e.g., claim 1 thereof.

Claim 34, which is directed to a pharmaceutical composition comprising a compound of formula (I) as set out in claim 1, is amended to render it independent. The language of canceled compound claim 1 is included, although without the option for R1, R2, R3 and R4 of "heterocyclyl".

Compound claims 3-32 have been canceled. New claims 35-64 depend from claim 34. They are directed to a pharmaceutical composition, and are adopted from claims 3-32. The option for R1, R2, R3 and R4 of "heterocyclyl" has not been included, however.

New claim 65 is also dependent upon claim 34. It is directed to a pharmaceutical composition comprising a compound which is selected from the compound of Example 55, Example 54, or Example 49.

New claim 66 is directed to a compound in which R6 is alkyl. The priority application provides support, e.g., from claim 12 thereof. New compound claims 67-70 are adapted from claims 4-7, and depend from new claim 66. These claims are also supported from the priority document, e.g., claims 14, 10, 15, and 17 thereof, respectively.

New claims 71 and 72 are directed to compounds which were presented in the priority application. The first two compounds are listed in the priority document in claim 20 as compound numbers 1 and 4. The third compound is listed in claim 19 as compound number 15. As requested by the Examiner during the interview, claim 72 is presented in complete form in that it lists the compounds referred to from claim 71 from which it depends.

Applicants request rejoinder of withdrawn process claim 33. The claim is amended herein to delete "heterocyclyl" as an option for R1, R2, R3 and R4. As discussed during the interview with the Examiner, claim 33 is also amended such that the compounds of formula (I) have the same scope as the compound covered in currently amended claim 2. This subject matter is also supported by the priority document, for example, process claim 31 therein.

During the interview, the Examiner indicated that the claim term, "pharmaceutically acceptable" in reference to hydrates, is redundant. Claims 1 and 2 are amended to remove the term as a modifier for hydrates. Similarly, new claims 45, 46, 48, 50, 52, 54, 56, 58, 60, 62, 65, and 71 do not include this term to modify hydrates.

No new matter is added by the claim amendments.

Reconsideration and withdrawal of the rejections are requested.

Claims 1-7 and 34 have been rejected under 35 USC 112, first paragraph, as not enabled. As noted above, the claims have been amended to delete "heterocyclyl" as an option for R1, R2, R3, and R4, and new claims similarly do not include this option. The Examiner indicated during the interview that this amendment overcomes the rejection.

Claims 1-8 and 32 have been rejected under 35 USC 102(a) as anticipated by the Bentley WO '169 publication. Also, claims 20-31 have been rejected as obvious over Bentley WO '169.

As claims 20-31 have been canceled, the rejection under section 103 has been obviated.

With regard to the Examiners' remarks concerning the section 102 rejection, certain of the Bentley WO '169 compounds noted are synthetic starting materials or intermediates, eg, formula D1 shown in the reaction schemes on page 9. In such compounds, the pyrazinoindole ring structure contains a double bond in the middle ring. There is no assertion of a pharmaceutical utility provided in Bentley for any such compounds. Other compounds noted by the Examiner are the claimed compounds of Bentley WO '169 such as listed on page 51. Such compounds are encompassed by the formula I genus and they have a saturated middle ring of the pyrazinoindole ring structure.

Claim amendments provide compound coverage, namely amended claim 2 and new claims 66-72, that obtain support from the priority application. Bentley WO '169 is not a competent prior art reference as to these claims. Therefore, the section 102 rejection has been overcome as to claim 2. Moreover, a section 102 rejection would not apply as to new claims 66-72.

Claim 34 which is directed to a pharmaceutical composition, is in condition for allowance as the Examiner has indicated that the section 112 rejection, the only outstanding rejection of this claim, is overcome by the amendment to R1, R2, R3, and R4. As noted above, new claims 35-65 have been added which depend ultimately from claim 34. The Bentley synthetic intermediates do not anticipate the claimed pharmaceutical composition, as each and every element of the claim is not found in the reference. As discussed with the Examiner, claims directed to a pharmaceutical

composition are not rendered obvious by species in Bentley WO '169 that are reported to be synthetic starting materials or intermediates, with no indication of a pharmaceutical utility. In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984) (no motivation is accorded to interrupt a prior art synthesis to determine properties of intermediates). Compounds reported in Bentley WO '169 which are asserted therein as having pharmaceutical utility, eg, formula I compounds, differ structurally from the claimed compounds in the saturation of the core ring structure. Such compounds of Bentley WO '169 do not anticipate or render obvious the claimed pharmaceutical composition which comprises a compound of instant formula I.

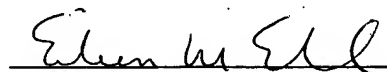
It is respectfully submitted that the claim amendments obviate the rejections under 35 USC 102 and 103 as to the Bentley WO '169 reference.

The provisional rejection under 35 USC 102(e) of anticipation and the provisional rejection under 35 USC 103 of obviousness over US Publication No. 10/396242 which is related to Bentley WO '169, are overcome in view of the arguments presented addressing Bentley WO '169.

As it is believed that the present application is in condition for allowance, issuance of a Notice of Allowance is respectfully requested.

A Petition for Extension of Time – 2 months – is enclosed. If the required fee is missing or deficient, please charge out deposit account no. 08-2525.

Respectfully submitted,



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